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March 10, 2006

Diane Beeson, PhD.
Professor Emerita
Department of Sociology and Social Services
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Hayward, CA 94542

Re: Subcommittee Hearing, "Human Cloning and Embryonic Stem Cell Research after Seoul: Examining exploitation, fraud and ethical problems in the research"

Dear Dr. Beeson:

Thank you very much for your testimony on March 7, 2006 before the Subcommittee on Criminal Justice, Drug Policy and Human Resources. Due to the limited amount of time available for the hearing, however, we were unable to address all of the issues involved. To better help the Subcommittee understand these significant issues, we are submitting to you the attached list of questions for the record.

In order to help the Subcommittee move forward with its work on this subject, we request that you respond to these questions in writing no later than the close of business on Friday, April 7, 2006. Your answers will be included in the written record.

Thank you very much for your time and assistance. If you have any questions, you may have a member of your staff contact Malia Holst at 202-225-2577.

Sincerely,

Mark E. Souder
Chairman
Subcommittee on Criminal Justice,
Drug Policy and Human Resources

1. The National Academies of Science recommended some guidelines for egg donation in their proposed guidelines for Stem Cell Research.

- *Do the National Academies recommendations go far enough in protecting women from the dangers of egg extraction for research purposes?*
- *What more is needed?*

2. The idea of compensation for women's eggs is frequently discussed in order to ensure a large egg pool. One of the compensation proposals involves paying an income-based pay scale, so poor women would be paid less than wealthier women, so poor women wouldn't feel compelled by being offered a large sum of money for their eggs.

- *Is it possible to fairly compensate women for their eggs?*
- *How would an oocyte compensation program protect against the fact that poor women who need the money more than wealthier women would be more likely to put themselves through the unpleasant process of oocyte donation?*

3. Even if oocyte donation were safe, do you think it would still be exploitive to use women for their eggs?

4. Are you aware if a concern for women's rights was a driving force behind other countries' laws regulating egg donation and SCNT (such as Canada's Assisted Human Reproduction Act, which prohibits human cloning as well as the buying and selling of female eggs)?

5. Please see attached information from Do No Harm, which concludes that based on published data, in order to provide genetically matched embryonic stem cells derived from cloning to treat the potential national patient pool, scientists would have to obtain at least 670 million eggs, donated by at least 67 million women.

- *What do you think are the foreseeable effect of such a huge demand for oocytes?*

6. Some people think that women should be able to decide for themselves whether or not they want to donate their eggs to science.

- *What do you say to the charge that it is being paternalistic to establish a policy, such as a moratorium on SCNT, that essentially deprives women of the choice to do so?*

7. You mentioned in your written testimony a Dutch study that indicates problems in the offspring of mice that have undergone ovarian hyperstimulation.

- *Could you explain why that is significant for humans?*

8. *What would be the most difficult problems to overcome in allowing therapeutic cloning, SCNT to move forward?*

9. *Do you know of cases where women have been rendered infertile or have died as a result of egg extraction?*

10. *Why do you propose separating IVF services from egg extraction for research purposes?*

Attachment

Source: Do No Harm: The Coalition of Americans for Research Ethics www.stemcellresearch.org

Potential U.S. Patient Populations for Stem Cell-Based Therapies (according to the National Academy of Sciences)[1]

Condition	Number of Patients
Cardiovascular disease	58 million
Autoimmune diseases	30 million
Diabetes	16 million
Osteoporosis	10 million
Cancers	8.2 million
Alzheimer's disease	5.5 million
Parkinson's disease	5.5 million
Burns (severe)	0.3 million
Spinal-cord injuries	0.25 million
Birth Defects	0.15 million

These numbers give a total patient population of 133.9 million. But as the NAS notes, these conditions "occur in many forms and thus not every person with these diseases could potentially benefit from stem cell therapies." Conservatively, let us say that perhaps 10% of the total will be eligible for such therapies, or 13.4 million.
Now, given the inefficiencies associated with cloning, consider the estimated number of oocytes (eggs) and donors that would be needed to treat disease as envisaged by cloning proponents:
Assume 20% cloning efficiency,[2]
Assume 10% efficiency at initiating an embryonic stem (ES) cell culture (from stem cells harvested from the cloned embryo).[3]
Assume that one could collect 10 eggs per donor.[4]

IN ORDER TO PROVIDE GENETICALLY MATCHED EMBRYONIC STEM CELLS DERIVED FROM CLONING TO TREAT THE POTENTIAL PATIENT POOL, SCIENTISTS WOULD HAVE TO OBTAIN AT LEAST 670 MILLION EGGS, DONATED BY AT LEAST 67 MILLION WOMEN.
WHERE WILL ALL THESE EGGS COME FROM?

[1] Stem Cells and the Future of Regenerative Medicine, National Research Council/Institute of Medicine, The National Academy of Sciences, available online at: http://books.nap.edu/html/stem_cells/reportbrief.pdf

[2] This is based on published reports of animal clones reaching the blastocyst stage (the stage at which stem cells develop) and NOT live birth. For example, 20 to 30 percent of cattle cloned by Advanced Cell Technology (ACT, the company which in November announced cloning the first human embryos) reach the blastocyst stage. With other species the range has been < 10 % up to 39%. Using both parthenogenesis and somatic cell nuclear transfer, ACT experienced a 100% failure rate in its 41 attempts to create human cloned embryos that would develop into a source for stem cells. None of the human clones created by SCNT reached the blastocyst stage. None of the embryos created by parthenogenesis could produce embryonic stem cells.

[3] James Thomson, of the University of Wisconsin, used 36 embryos to derive 5 human ES cell lines (13.8%). The Jones Institute used 110 embryos to get three lines (2.7%). When Wakayama et al. cloned mice and harvested ES cells, they had a 3.4% efficiency.

[4] ACT collected 71 eggs from 7 donors – "The [ACT] researchers hoped to collect about two dozen eggs a month from donors, but even that was an ambitious goal, and when the eggs did arrive there were often only five or 10 to work with," Joannie Fischer, "The First Clone," U.S. News and World Report, 12/3/01.